

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA  
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	* MDL Docket No. 2004
	4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*
	Case Nos.
LIABILITY LITIGATION	* 4:14-cv-99 (Chock)

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O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Genevieve Chock was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Mrs. Chock brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Mrs. Chock also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Her husband Roman asserts a loss of consortium claim. Mentor seeks summary judgment on all of Plaintiffs' claims. For the reasons set forth below, Mentor's summary judgment motion (ECF No. 30 in 4:14-cv-99) is granted in part and denied in part. Plaintiffs seek leave to amend their complaint to add a claim for punitive damages. That motion (ECF No. 32 in 4:14-cv-99) is granted.

## SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

## FACTUAL BACKGROUND

Plaintiff Genevieve Chock experienced symptoms of stress urinary incontinence. On May 23, 2005, Dr. Curtis Keller implanted Mrs. Chock with ObTape to treat her stress urinary incontinence. Before he implanted Mrs. Chock with ObTape, Dr. Keller attended a training seminar on the technique used to implant ObTape. He would have reviewed the ObTape product insert data sheet before performing an ObTape implant. Keller Dep. 34:7-11, ECF No. 33-24 in 4:14-cv-99; see also *id.* 60:21-23 (testifying that Dr. Keller implanted ObTape in accordance with the product insert data sheet); *id.* at 104:6-11 ("I'm sure I

received literature from Mentor for myself, but not for patients." ). If Mentor had told Dr. Keller that his patients might develop recurrent urinary tract infections and chronic pelvic pain related to the ObTape, that may have impacted his decision to implant Mrs. Chock with ObTape; at the least, he would have sought informed consent from Mrs. Chock. *Id.* at 34:17-36:10; 74:18-75:6. If Dr. Keller had informed Mrs. Chock that she could develop chronic pain and recurring urinary tract infections related to ObTape, Mrs. Chock would not have undergone the ObTape procedure. Chock Dep. 87:19-88:13, ECF No. 33-4 in 4:14-cv-99.

Dr. Keller told Mrs. Chock that there was a "9 out of 10" chance that the ObTape would work to help her stress urinary incontinence. Keller Dep. 102:1-5. For two years following the implant surgery, Mrs. Chock did not report incontinence or any other issues with her ObTape. But starting in 2007, Mrs. Chock sought treatment from multiple doctors for urinary tract infections, pain, and recurrent incontinence. She attributes those symptoms to ObTape, although none of her treating physicians have told her that the symptoms are related to ObTape.

Dr. Andrew Siegel, a board certified urologist and Mrs. Chock's general causation expert, opined that the physical properties of ObTape can prevent tissue ingrowth and can cause

chronic inflammation. Cook Decl. Ex. W, Siegel Report 4, ECF No. 33-25 in 4:14-cv-99. Dr. Siegel also opined that the physical properties of ObTape can cause pain and organ dysfunction. *Id.* Dr. Amanda White, a board certified urogynecologist and Mrs. Chock's specific causation expert, also opined that ObTape's physical properties rendered it "prone to infection and extrusion." Cook Decl. Ex. A, White Report 3, ECF No. 33-3 in 4:14-cv-99.

Dr. White reviewed Mrs. Chock's medical records and relied on her own extensive experience with urethral slings. Based on her review, Dr. White concluded that "ObTape is a substantial contributing cause of Ms. Chock's chronic bladder symptoms, including urgency and frequency, recurrent urinary tract infections, and nocturia." White Report 8. She also opined that Mrs. Chock's "recurrent urinary tract infections were likely caused by the material properties of the ObTape device." *Id.* She also opined that "[t]he material properties of the ObTape transobturator sling, namely unwoven, thermally bonded polypropylene microporous mesh are such that tissue in-growth with capillary penetration is prohibited. While bacteria are able to enter the graft, host defense mechanisms are unable to respond within the device secondary to the size of leukocytes and macrophages. The result is an encapsulated graft with acute and chronic inflammation." *Id.* at 9.

Mrs. Chock asserts claims for strict liability, negligence, design defect, manufacturing defect, failure to warn, and breach of express and implied warranties. Mr. Chock asserts a loss of consortium claim. Mentor seeks summary judgment on all of these claims. Mrs. Chock does not challenge Mentor's summary judgment motion on her warranty claims, so the Court grants Mentor's summary judgment motion as to those claims.

#### DISCUSSION

Plaintiffs filed their action in this Court on April 23, 2014 under the Court's direct filing order. The parties agreed that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. Plaintiffs live in Minnesota, and all of Mrs. Chock's ObTape-related treatment took place in Minnesota. The parties agree that Minnesota law applies to the Plaintiffs' claims.

#### **I. Design Defect Claims**

Mrs. Chock brings design defect claims under negligence and strict liability theories, asserting that ObTape had a design defect that caused her injuries. Mentor argues that Mrs.

Chock's claims fail for lack of specific causation. The Court disagrees.<sup>1</sup>

Mentor asserts that Mrs. Chock did not point to sufficient evidence to establish specific causation: that ObTape actually caused Mrs. Chock's injuries. Again, Dr. White opined that based on her review of Mrs. Chock's medical records, ObTape more likely than not was a substantial contributing cause of Mrs. Chock's injuries, including her recurrent urinary tract infections and pelvic pain. Dr. White further opined that the material properties of ObTape inhibited tissue ingrowth and permitted bacteria to enter the graft while preventing defense mechanisms like leukocytes and macrophages from responding—leading to Mrs. Chock's injuries. Mentor contends that the Court should exclude Dr. White's opinion because her report does not detail, to Mentor's satisfaction, how Dr. White reached this conclusion. But Mentor did not file a *Daubert* motion seeking to exclude Dr. White's testimony, and the Court notes that Dr. White has not been deposed in this action. The Court declines to exclude Dr. White's testimony on this basis.

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<sup>1</sup> Mentor does not appear to contend that Mrs. Chock did not point to enough evidence to establish general causation: that ObTape is capable of causing the types of injuries Mrs. Chock suffered. Mrs. Chock asserts that she suffered chronic infections and pain. Dr. Siegel opined that ObTape is capable of causing these types of injuries due to its physical properties. This evidence is sufficient to create a genuine fact dispute on general causation.

Mentor also asserts that because Mrs. Chock's treating physician believes that Mrs. Chock's urinary tract infections and chronic pain (at least through 2012) were not caused by ObTape, the Court should ignore Dr. White's opinion. Based on the present record, the Court is not convinced that the difference in opinion between Mrs. Chock's treating physician and Dr. White is a valid basis for excluding Dr. White's opinion at this time. The Court thus declines to ignore Dr. White's opinion and finds that it is sufficient to create a genuine fact dispute on specific causation. For these reasons, the Court denies Mentor's summary judgment motion as to Mrs. Chock's design defect claims. The Court likewise denies Mentor's summary judgment motion as to Mr. Chock's loss of consortium claim, which is derivative of Mrs. Chock's claims. *See Kohler v. Fletcher*, 442 N.W.2d 169, 173 (Minn. Ct. App. 1989) (noting that a husband's loss of consortium claim is derivative of his wife's underlying tort claim).

## **II. Failure To Warn Claims**

Mrs. Chock brings failure to warn claims under strict liability and negligence theories, contending that Mentor did not adequately warn her physicians about the true risks of ObTape. Mentor argues that Mrs. Chock has not presented enough evidence to create a genuine fact dispute on causation for these claims.

Under Minnesota law, a plaintiff claiming a failure to warn must show that "the lack of an adequate warning caused the plaintiff's injuries." *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004) (applying Minnesota law). Thus, to establish causation on her failure to warn claims under Minnesota law, Mrs. Chock must show that a different warning or an accurate disclosure of the risks of ObTape would have made a difference in her treatment. There must be some evidence that the product user (or, in cases like this one where the learned intermediary doctrine applies, the product user's doctor) "would have acted differently had the manufacturers provided adequate warnings." *Id.*

Mentor argues that Mrs. Chock cannot establish a failure to warn claim because Mrs. Chock did not suffer the precise type of injury she claims Dr. Keller should have been warned about, such as an erosion or an infection. But Mrs. Chock does contend that Dr. Keller was not adequately warned of the risk of recurrent late-onset infections and that she suffered such infections related to her ObTape. As discussed above, Mrs. Chock's expert witnesses opined that ObTape's physical characteristics make it susceptible to a number of complications that can cause problems; the same characteristics that can cause erosions can also result in infections like the ones Mrs. Chock experienced.



Mrs. Chock pointed to evidence that Dr. Keller reviewed Mentor materials, including the ObTape product insert data sheet, before he began using ObTape. Mrs. Chock also presented evidence that if Mentor had provided Dr. Keller with accurate information about ObTape's pore size and its risks, Dr. Keller may have considered a different product for Mrs. Chock and at least would have sought informed consent from Mrs. Chock. And Mrs. Chock presented evidence if Dr. Keller had sought informed consent from her based on ObTape's true risks, Mrs. Chock would not have undergone the implant surgery. This evidence is sufficient to create a genuine fact dispute on causation for Mrs. Chock's failure to warn claims. Mentor is therefore not entitled to summary judgment on these claims.

### **III. Plaintiffs' Motion to Add Punitive Damages Claim**

Plaintiffs seek leave to add a claim for punitive damages. To be entitled to punitive damages under Minnesota law, a plaintiff must establish by "clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others." Minn. Stat. Ann. § 549.20 subd. 1(a). A plaintiff may not seek punitive damages in her initial complaint. *Id.* § 549.191. Rather, "[a]fter filing the suit a party may make a motion to amend the pleadings to claim punitive damages." *Id.* "The motion must allege the applicable legal basis under [Minn. Stat. Ann. § ] 549.20 . . . for awarding

punitive damages in the action and must be accompanied by one or more affidavits showing the factual basis for the claim.” *Id.* “The Court must give the plaintiff leave to add a claim for punitive damages if it finds that the plaintiff provides prima facie evidence in support of the motion [to amend].” *Merry v. Prestige Capital Markets, Ltd.*, 944 F. Supp. 2d 702, 711 (D. Minn. 2013) (citing *Swanlund v. Shimano Indus. Corp.*, 459 N.W.2d 151, 154 (Minn. Ct. App. 1990)).

Based on the Court’s review of Plaintiffs’ motion, which is supported by an affidavit and eighty-one exhibits—most of which detail the information that was available to Mentor regarding ObTape’s risks—the Court is satisfied that Plaintiffs have presented prima facie evidence to support the requested amendment. Plaintiffs’ motion for leave to file an amended complaint to add a claim for punitive damages (ECF No. 32 in 4:14-cv-99) is therefore granted.

#### CONCLUSION

As discussed above, Mentor’s summary judgment motion (ECF No. 30 in 4:14-cv-99) is granted as to Mrs. Chock’s warranty claims but denied as to Mrs. Chock’s design defect claims, failure to warn claims, and Mr. Chock’s loss of consortium claim. Plaintiffs’ motion for leave to file an amended complaint to add a claim for punitive damages (ECF No. 32 in 4:14-cv-99) is granted. This action is ready for trial. Within

seven days of the date of this Order, the parties shall notify the Court whether they agree to a *Lexecon* waiver.

IT IS SO ORDERED, this 19th day of December, 2016.

S/Clay D. Land

CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE  
MIDDLE DISTRICT OF GEORGIA